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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/641,892	08/18/2000	Hiroshi Izui	195942US0	6721
22850	7590	11/12/2004		
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER LAMBERTSON, DAVID A	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 11/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/641,892

Applicant(s)

IZUI ET AL.

Examiner

David A. Lambertson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Receipt is acknowledged of a reply to the previous Office Action, filed September 20, 2004. Amendments were made to the claims.

Claims 1-24 are pending and under consideration in the instant application. Any rejection of record in the previous Office Action, mailed March 19, 2004, that is not addressed in this action has been withdrawn.

Because this Office Action only maintains rejections set forth in the previous Office Action and/or sets forth new rejections that are necessitated by amendment, this Office Action is made FINAL.

Miscellaneous

Applicant's declaration under 37 CFR § 1.132 has been considered.

Claim Rejections - 35 USC § 112

Claims 1-10, 14 and 17-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This rejection is maintained for the reasons set forth in the previous Office Action.**

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Claims 1-10, 14 and 17-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. **This rejection is maintained for the reasons set forth in the previous Office Action.**

Response to Arguments Concerning Claim Rejections - 35 USC § 112

Applicant's arguments filed September 20, 2004 concerning the Written Description rejection have been fully considered but they are not persuasive. The following grounds of traversal are presented:

Applicant asserts that, because Applicant has described a method of screening for (and thus identifying) the claimed microorganism, they have satisfied the Written Description requirement by showing they were in possession of the claimed genus of microorganisms (see for example page 8-9, bridging paragraph of Applicant's response).

Applicant's traversal is not convincing for the following reasons:

Applicant's own argument indicates the lack of a written description with regard to the broadly claimed invention. Applicant correctly points to MPEP§ 2163.02, where it indicates the Written Description requirement requires the ordinary skilled artisan to recognize the claimed invention. Applicant also states that the claimed strains can be *identified* by a screening process, thus they were in possession of the claimed genus. However, it is unclear how one can possess something that has yet to be identified, and no rational explanation is provided concerning this issue in the response. The salient feature of the rejection is that there is no correlation between a

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structural feature of a microorganism (i.e., a genetic alteration) that necessarily results in the desired function (i.e., the ability of the strain to both survive/grow and produce glutamic acid at saturated levels of glutamic acid). For example, if the specification had described that a mutation in the activity of "gene X" resulted in the ability of a microorganism to both survive/grow and produce glutamic acid at saturated levels of glutamic acid, then the skilled artisan would recognize which microorganisms had the desired function by virtue of the mutation of the structural element responsible for that function. A method of screening for microorganisms does not bridge the gap between structure and function, and essentially represents a method of trial and error experimentation. As such, Applicant's argument is insufficient to establish that the Written Description requirement has been met.

It is important to note that Applicant argues that the teachings of Moriya are not anticipatory over the instant invention (see Applicant's traversal of the rejection under 35 USC 102(e), pages 11-12 of Applicant's response). This argument exemplifies the lack of Written Description of the instant invention, because one of skill in the art has no way of envisioning whether those strains disclosed in Moriya have the desired functional properties. Applicant simply dismisses Moriya as anticipatory art because "from the inventors knowledge" those strains do not have the desired property; Applicant provides no scientific explanation for why these strains do not have the functional property as claimed (such as the strains either have too much of or lack a particular enzymatic activity). Because the instant specification fails to describe the structural element (i.e., a gene or mutation thereof) that is responsible for conferring upon a microorganism the functional ability to survive and then continue to produce L-glutamic acid at saturating concentrations of the amino acid, the skilled artisan has no way of envisioning

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which strains do or do not have these properties (as per the allegation regarding the strains taught by Moriya). Without such a description, the skilled artisan is left to wonder what must or must not be done to a microorganism in order to confer upon it the desired property of the invention. Thus, the rejection under Written Description is maintained.

Applicant's arguments filed September 20, 2004 concerning the Enablement rejection have been fully considered but they are not persuasive. The following grounds of traversal are presented:

1. Applicant asserts that, because Applicant has described a method of screening for (and thus identifying) the claimed microorganism, they have satisfied the Enablement requirement by showing the claimed microorganism can be obtained by the screening method (see for example page 9, second full paragraph of Applicant's response).
2. Applicant provides several references describing the enzymes involved in glutamic acid biosynthesis in a number of microorganisms. Applicant summarizes the references, and concludes by alleging that other microorganisms besides an *Enterobacter* can represent the claimed invention (see for example page 9, bottom paragraph of Applicant's response).
3. Applicant refers to a declaration by inventor Hara, wherein an experiment is reported disclosing strains having improved resistance to high concentration of L-glutamic acid, and concludes that this would allow the skilled artisan to make and use the claimed invention (see for example pages 10-11 of Applicant's response).

Applicant's arguments are not convincing for the following reasons:

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1. As stated before, a method for identifying microorganisms is not equivalent to a method for “making and using” a microorganism. The fact of the matter is that neither the specification nor the prior art establishes a structure-function relationship for the ability of a microorganism to survive and further produce L-glutamic acid in a medium where the concentrations of L-glutamic acid are at an inhibitory concentration (i.e., its saturation concentration). Without this structure-function relationship, the skilled artisan could not take a given microorganism as a starting material and convert it into one that has the ability to survive and further produce L-glutamic acid at its saturation concentration). This is also evident from Applicant’s arbitrary dismissal of Moriya *et al.* as non-anticipatory art, without any explanation as to how the skilled artisan could pick a microorganism having a given genotype, and decide whether or not it had the functional properties of the claimed invention. In other words, only the inventors “personal knowledge” can discern whether a given microorganism meets the functional limitations of the instant invention. Therefore, the skilled artisan cannot make and subsequently use the claimed microorganism without undue and unpredictable experimentation (i.e., randomly screening for an organism with the desired activity).

2. None of the references cited refers to a structural feature of a microorganism that confers the ability of a microorganism to both survive/grow and produce glutamic acid at saturated levels of glutamic acid, therefore none of the references can be used to overcome the unpredictability associated with the claimed invention. Again, in order to make and subsequently use the claimed microorganisms, the skilled artisan must be able to take a structural feature (i.e., a gene(s)) from a microorganism and confer upon a different microorganism the desired property associated with the structural feature. This is not present in either the instant specification or the prior art. What

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the prior art provided herein describes is the genes that are involved in glutamic acid biosynthesis; however, these genes are not relevant to the ability to survive/grow and produce glutamic acid at already saturated concentrations of glutamic acid.

3. The declaration refers to randomly generated bacterial strains that are not even disclosed in the instant specification, with the exception of one (G106, disclosed as AJ13601; notably, this strain is not specifically claimed). The fact that these strains are randomly generated through mutagenesis accentuates the unpredictability associated with making the claimed invention. For instance, there is no part of the specification that teaches how to specifically make strain G1 of the Hara declaration, as opposed to strain G2 or G3, etc. If the specification fails to teach how to make specific strains of the claimed invention, it must also fail how to teach the collective genus of those embodiments. The skilled artisan is unable to make any of these strains in a predictable manner because it is unknown: (1) if each strain results from the mutation of one or multiple genes (i.e., how many genes are responsible for conferring the desired property), (2) what the identity of the gene(s) is, (3) if the mutations are the result of a single mutation in one gene, or multiple mutations in the same gene, etc. There is simply no indication of what gene or genes must be mutated in order to confer upon a microorganism the biochemical property of surviving/continuing to produce L-glutamic acid in the presence of saturating concentrations of L-glutamic acid. Without knowing which genes to mutate, the skilled artisan cannot make the claimed strains without unpredictable trial and error experimentation.

In response to Applicant's arguments, it is reiterated that the instant specification and the prior art fails to disclose a structural feature that confers upon a microorganism the ability to survive/grow and produce glutamic acid at already saturated concentrations of glutamic acid.

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Furthermore, Applicant simply dismisses an applied reference of anticipatory art as not having the functional properties of the claimed invention, yet fails to explain why these strains do not meet the functional limitations. In the absence of such a structural feature, the skilled artisan cannot make any microorganism that has such a desired property because the skilled artisan does not know what must be altered within a strain to give it a specific property. Instead, the skilled artisan would be left to random screening and unpredictable experimentation to determine if any given microorganism retained the desired function; therefore the broad scope of the claims lacks enablement.

Double Patenting

Claims 10-13 and 15-24 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 5-8 of copending Application No. 10/077,751, now US Application 6,720,010. **This rejection is maintained for the reasons set forth in the previous Office Action.**

Response o Arguments Concerning Double Patenting

Applicant requests that this rejection be held in abeyance until the indication of allow subject matter. Because Applicant has not provided an argument traversing the rejection, the rejection is maintained.

Allowable Subject Matter

No claims are allowed.

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THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (571) 272-0771. The examiner can normally be reached on 6:30am to 4pm, Mon.-Fri., first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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AU 1636



JAMES KETTER
PRIMARY EXAMINER